8EHG-0993-12429



CHEMICAL MANUFACTURERS ASSOCIATION

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COMPANY SANITIZED

September 15, 1993

## VIA CERTIFIED MIAL

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Attention: Section 8(e) Coordinator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

8EHQ-93-12425 SPODI 89930000166

Re: TSCA Section 8(e) Reporting/Notification for Methyl Bromide

Dear Sir or Madam:

The Chemical Manufacturers Association (CMA) hereby submits for your office's information, notice of two reports regarding methyl bromide (CAS No. 74-83-9) that have been submitted to EPA pursuant to Section 6(a)(2) of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). This notification is made on behalf of the members the Methyl Bromide Industry Panel. The Panel consists of TriCal, Inc., Ameribrom, Inc., Ethyl Corp., and Great Lakes Chemical Corp.

The reported information stems from two aquatic toxicity studies being conducted pursuant to EPA's Methyl Bromide Data Call-In issued under Section 3 of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). Specifically, these studies are identified as: 1) Fish Toxicity Study with Rainbow Trout; and 2) Invertebrate Toxicity Study with Daphnia magna. Both studies are required for the continued registration of methyl bromide as a pesticide.

Based upon the explicit exemption for pesticides contained in Section 3 of the Toxic Substances Control Act (TSCA), and EPA's TSCA 8(e) Statement of Interpretation and Enforcement Policy, the Panel believes that both studies are not subject to TSCA Section 8(e) reporting requirements.

The Panel sought confirmation of this understanding from EPA officials in both the Office of Pesticide Programs and the Office of Pollution Prevention and Toxics, but received conflicting opinions regarding the application of TSCA to chemicals also regulated under FIFRA. In light of the lack of a consistent policy on the applicability of TSCA to chemicals regulated under FIFRA,

Document Processing Center September 15, 1993
Page 2

the Panel is notifying the TSCA 8(e) Coordinator of the attached submission to the Office of Pesticide Programs as a precaution.

The filing of this notice does not authorize any use of the information by any person outside the EPA Office of Pesticide Programs or any other release of the reported information to the public. The studies are the property of the Methyl Bromide Industry Panel and its members and, as such, must be protected by the Agency from public disclosure.

If you have any questions regarding this notice, please call me at 202/887-1293.

Sincerely,

Kathryn A. Rosica

Manager

Methyl Bromide Industry Panel

Attachments



September 15, 1993

#### VIA CERTIFIED MAIL

FIFRA Section 6(a)(2)
Document Processing Desk
Office of Pesticide Programs - H7504c
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001
Attention: Ruth R. Douglas, Product Manager, PM-32

Re: FIFRA Section 6(a)(2) Report

Dear Ms. Douglas:

On behalf of the Methyl Bromide Industry Panel (MBIP), the Chemical Manufacturers Association submits the attached information pursuant to Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the EPA guidance on Section 6(a)(2) reporting requirements published in the Federal Register on July 12, 1979 (1979 Guidance). The MBIP consists of three manufacturers of technical product -- Ameribrom, Inc., Ethyl Corporation, and Great Lakes Chemical Corporation -- and one major formulator, TriCal, Inc.

Pursuant to the 1991 Methyl Bromide Data Call-In, the MBIP is jointly sponsoring an Invertebrate Toxicity Study (Guideline No. 72-2(a) with Daphnia Magna. The attached, preliminary data has been received from the conducting laboratory, and constitutes information not previously reported to the Agency regarding the toxicity of methyl bromide to aquatic organisms. Thus, in accordance with EPA guidance regarding the submission of preliminary or incomplete study results, this information is hereby reported. The final study report will be submitted to the Agency on October 1, 1993.

 $<sup>\</sup>frac{1}{2}$  44 Fed. Reg. 40716 (July 12, 1979).

<sup>2/ &</sup>lt;u>See</u> 40 Fed. Reg. 40716, 40718.

FIFRA Section Document Processing Desk September 15,7 1993 Page 2

If you have any questions concerning these reports, please call me at (202) 887-1293.

Sincerely,

Kathryn A. Rosica

Manager

Methyl Bromide Industry Panel

Attachments

BEST COPY AVAILABLE Consulative Percent Mortality and Treatment-Related Effects

Sponsor: Methyl Bromide Industry Panel
Chemical Manufacturers Association
Test Organism: Cladoceran, <u>Dechnia magna</u>
Dilution Water: Well Water

Sponsors

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Observed Effects: AM # Appears Mormel; C'm Lethargy.



September 15, 1993

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FIFRA Section 6(a)(2)
Document Processing Desk
Office of Pesticide Programs - H7504c
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001
Attention: Ruth R. Douglas, Product Manager, PM-32

Re: FIFRA Section 6(a)(2) Report

Dear Ms. Douglas

On behalf of the Methyl Bromide Industry Panel (MBIP), the Chemical Manufacturers Association submits the attached information pursuant to Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the EPA guidance on Section 6(a)(2) reporting requirements published in the Federal Register on July 12, 1979 (1979 Guidance). The MBIP consists of three manufacturers of technical product -- Ameribrom, Inc., Ethyl Corporation, and Great Lakes Chemical Corporation -- and one major formulator, TriCal, Inc.

Pursuant to the 1991 Methyl Bromide Data Call-In, the MBIP is jointly sponsoring a Fish Toxicity Study (Guideline No. 72-1(c) with Rainbow Trout. The attached data was generated during a preliminary phase of the Study to determine dose ranges, and constitutes information not previously reported to the Agency regarding the toxicity of methyl bromide to aquatic organisms. Thus, in accordance with EPA guidance regarding the submission of preliminary or incomplete study results, this information is hereby reported. A final study report will be submitted to the Agency on January 15, 1994.

<sup>1/ 44</sup> Fed. Reg. 40716 (July 12, 1979).

<sup>2/ &</sup>lt;u>See</u> 44 Fed. Reg. 40716, 40718.

FIFRA Section Document
Processing Desk
September 15, 1993
Page 2

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Sincerely,

Kathryn A. Rosica

Manager

Methyl Bromide Industry Panel.

Attachments

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WILDLIFE INTERNATIONAL LTD. RESULTS OF RANGE-FINDING TEST WITH THE	Dealtalasmy morally and auditary to deal
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Preliminary results not audited by Quality Assurance RAINBON TROUT

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SP	OMSOR: St subs	SPONSOR: CMA TEST SUBSTANCE: Methyl Bromide		WIL PROJECT NO.: 264A-104 START DATE: 08/30/93	AS SA
Kominai		~	Kumber Alive/Number	Mumber Alive/Mumber Exposed (Observations)	
concentration (mg/L)	Rep.	8	48 Kours	72 Hours	96 Hours
Control	≪∞:				
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Observations: AN - Appears Mormal, C - Lethardy, D - Discoloration, M - Loss of Equilibrium treatment group (~2 mg/L)

Proposed Concentrations for Definitive Test: Control, 1.0, 1.7, 2.9, 4.8, and 8.0 mg/l

92609555



P.02

## **BEST COPY AVAILABLE**

## FRESH WATER CHEMISTRY (Test Termiation)

DRAFT (a)

HAS NOT RECEIVED QA AUDIT

TEST: Rainbow Trout 96-Hour Static Range-Finding SPONSOR: CMA PROJECT NUMBER: - 264A-104 TEST SUBSTANCE: Methyl Bromide

TEST SUBSTANCE:	Methyl Bromide			
Nominal Test Concentration (mg/L)	Replicate	Dissolved Oxygen (mg/L)	Hq	Temp.
0 (Control)	A	6.3	8.2	12.2
(00000000000000000000000000000000000000	В	6.4	8.2	12.1
	С	6.4	8.2	12.2
0.8	A	6.5	8.2	12.2
	В	6.5	8.2	12.2
	c	6.5	8.2	12.2
4.0	Α	6.7	8.3	12.1
	В	7.9	8.4	12.2
	C	7.8	8.3	12.1
20	A	7.9	8.4	12.1
	В	7.9	8.4	12.2
	С	8.0	8.4	12.2
50	A	8.1	8.4	12.2
•	В	8.0	8.4	12.2
	C	8.0	8.4	12.2

<sup>16.5</sup> mg/L and 4.3 mg/L represent 60% and 40% saturation at 12°C, respectively.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Kathryn A. Rosica Manager, Methyl Bromide Panel Chemical Manufacturers Association 2501 M Street, N.W. Washington, D.C. 20037

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

JAN 18 1954 1994

This letter formally acknowledges EPA's receipt of information submitted by your organization under Section 8(e), the "substantial risk" information reporting provision of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA Section 8(e) Document Control Number (i.e., 8EHQ-0000-0000 Init.) assigned by EPA to your submission(s). Please refer to this cited number when submitting follow-up or supplemental information.

Please note that all submitted correspondence will be placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA Section 8(e) policy statement (43 FR 11110, March 16, 1978).

Confidential submissions submitted pursuant to the TSCA Section 8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims, because substantiation of CBI claims is required at the same time the 8(e) CAP is submitted to EPA. (If not done so already, please ensure that this information is provided to the Agency). When substantiating any/all claims, answer the questions detailed in the following attachment.

For  $\underline{\text{NON-CAP}}$  submissions, any confidentiality claims should be supported by submission of information as described in the attachment(s).

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COMMENTS: Non-CAP



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93 SEP 20 CHENICA MANUFACTURERS ASSOCIATION

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8EHQ-0993-12425

September 17, 1993

VIA CERTIFIED MIAL

BEHQ-73-12425

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Attention: Section 8(e) Coordinator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

88930000442

Re: TSCA Section 8(e) Reporting/Notification for Methyl Bromide

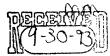
Dear Sir or Madam:

The Chemical Manufacturers Association (CMA) hereby submits for your office's information notice of information regarding methyl bromide (CAS No. 74-83-9) that has been submitted to EPA pursuant to Section 6(a)(2) of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). This notification is made on behalf of the members the Methyl Bromide Industry Panel. The Panel consists of TriCal, Inc., Ameribrom, Inc., Ethyl Corp., and Great Lakes Chemical Corp.

The reported information stems from a 90-Day Inhalation Neurotoxicity study being conducted pursuant to EPA's Methyl Bromide Data Call-In issued under Section 3 of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). The study is required for the continued registration of methyl bromide as a pesticide.

Based upon the explicit exemption for pesticides contained in Section 3 of the Toxic Substances Control Act (TSCA), and EPA's TSCA 8(e) Statement of Interpretation and Enforcement Policy, the Panel believes that the study is not subject to TSCA Section 8(e) reporting requirements.

The Panel has sought confirmation of this understanding from EPA officials in both the Office of Pesticide Programs and the Office of Pollution Prevention and Toxics, but received conflicting opinions regarding the application of TSCA to chemicals also regulated under FIFRA. In light of the lack of a consistent policy on the applicability of TSCA to chemicals regulated under FIFRA, the Panel is notifying the TSCA 8(e) Coordinator of the attached submission to the Office of Pesticide Programs as a precaution.



Document Processing Center September 17, 1993 Page 2

The filing of this notice does not authorize any use of the information by any person outside the EPA Office of Pesticide Programs or any other release of the reported information to the public. The information is the property of the Methyl Bromide Industry Panel and its members and, as such, must be protected by the Agency from public disclosure.

If you have any questions regarding this notice, please call me at 202/887-1293.

Sincerely,

Cathryn A. Posica

Manager

Methyl Bromide Industry Panel

Attachment



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September 17, 1993

VIA CERTIFIED MAIL

FIFRA Section 6(a)(2)
Document Processing Desk
Office of Pesticide Programs - H7504c
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001
Attention: Ruth R. Douglas, Product Manager, PM-32

Re: FIFRA Section 6(a)(2) Report

Dear Ms. Douglas:

On behalf of the Methyl Bromide Industry Panel (MBIP), the Chemical Manufacturers Association submits the attached information pursuant to Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the EPA guidance on Section 6(a)(2) reporting requirements published in the Federal Register on July 12, 1979 (1979 Guidance). The MBIP consists of three manufacturers of technical product -- Ameribrom, Inc., Ethyl Corporation, and Great Lakes Chemical Corporation -- and one major formulator, TriCal, Inc.

Pursuant to the 1991 Methyl Bromide Data Call-In (DCI), the MBIP is jointly conducting a 90-day Vapor Inhalation Neurotoxicity Study (Guideline No. 82-5(b). According to the 1979 Guidance, the Agency does not require the routine submission of information regarding preliminary or inconclusive testing results. Rather, registrants have 90 days or more after testing has been done to complete the final analysis of study results. 2/Nonetheless, some of the specific, preliminary results of the above-referenced Study may not be known by the Agency. Thus, as a precaution, the MBIP is advising EPA of the following information regarding the preliminary results of the Study:

Fifteen CD® rats/sex/group were exposed to methyl bromide vapor, CAS No. 74-83-9, by inhalation six hours/day, five days/week, for at least 13 weeks at target concentration of . Clinical signs of toxicity, body weight, food

<sup>1/ 44</sup> Fed. Reg. 40716 (July 12, 1979).

<sup>2/ &</sup>lt;u>See</u> 44 Fed. Reg. 40716, 40718.

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FIFRA Section Document Processing Desk September 17, 1993 Page 2

consumption, functional observations, motor activity, perfused brain weights, gross pathology, and histologic neuropathology were assessed. Rats scheduled for pathologic examination (10/sex/group) were sacrificed during the 14th week of exposure.

was statistically significant in the ppm exposure group during Weeks 4-13 for the females and during Weeks 5-13 for the males.

statistically significant in the ppm group during Weeks 9 and 11-13.

was statistically significant during Weeks 1-13 in the group, whereas the decrease in was statistically significant during Weeks 1-13 in the

was statistically significant during Weeks 1-13 in the ppm group and during Weeks 5-13 in the ppm group.

During Weeks 4, 8, and 13, males in the ppm group had a There was a statistically significant correlation between concentration and level of arousal for Weeks 8 and 13.

The analysis of the female data revealed statistically significant decreases in the and ppm groups at Week 13. Although not statistically significant, the results of Week 8 revealed a similar pattern. The in the number of for the females at ppm was statistically significant at Weeks 4, 8, and 13. There was not significant effects on t for males throughout the study. Histopathological observations included and

A detailed assessment and final analysis of these, and other results of the Study is in progress. In accordance with the DCI, the audited final study report will be submitted to EPA on October 1, 1993.

If you have any questions concerning this report, please call me at (202) 887-1293.

Sincerely,

Kathryn Al/Rosica

Manager

Methyl Bromide Industry Panel



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Kathryn A. Rosica Manager, Methyl Bromide Panel Chemical Manufacturers Association 2501 M Street, N.W. Washington, D.C. 20037

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

JAN 18 1994

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